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| APPLICATION NO.            | FILING DATE                     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|---------------------------------|----------------------|---------------------|------------------|
| 10/570,125                 | 10/23/2006                      | Albert J. Banes      | 4647-060533         | 7408             |
|                            | 7590 09/22/200<br>AW FIRM, P.C. | EXAMINER             |                     |                  |
| 700 KOPPERS<br>436 SEVENTH | BUILDING                        | GIBBS, TERRA C       |                     |                  |
| PITTSBURGH                 | =                               |                      | ART UNIT            | PAPER NUMBER     |
|                            |                                 |                      | 1635                |                  |
|                            |                                 |                      |                     |                  |
|                            |                                 |                      | MAIL DATE           | DELIVERY MODE    |
|                            |                                 |                      | 09/22/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(s) |  |  |  |  |
|--|---|--------------|--|--|--|--|
|  | 10/570,125  | BANES ET AL. |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit     |  |  |  |  |
|  | TERRA C. GIBBS  | 1635         |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |              |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |              |  |  |  |  |
| Status   |   |              |  |  |  |  |
| 1) Responsive to communication(s) filed on   |   |              |  |  |  |  |
|  | -<br>action is non-final.   |              |  |  |  |  |
| ·=   |   |              |  |  |  |  |
|  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |              |  |  |  |  |
| Disposition of Claims  |   |              |  |  |  |  |
| 4) Claim(s) 1-18 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) 1-18 are subject to restriction and/or election requirement.  |   |              |  |  |  |  |
| Application Papers   |   |              |  |  |  |  |
| <ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>  |   |              |  |  |  |  |
|  |   |              |  |  |  |  |
| Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some col None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |   |              |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date   | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:                        | te           |  |  |  |  |

Group I.

Claims 1-18 are pending in the instant application.

Claims 1-18 are subject to restriction as detailed below:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

strain of cells, comprising treating the cells with compounds that affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is a mediator which causes release of cell attachment

points of the cells from its extracellular matrix. If this Group is

Claims 8 and 9, drawn to a method for manipulating the intrinsic

elected, a further restriction is required as detailed below.

Group II. Claims 10 and 11, drawn to a method for manipulating the intrinsic

strain of cells, comprising treating the cells with compounds that

Application/Control Number: 10/570,125

Art Unit: 1635

affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is a ligand that modulates attachment and tensional structuring of the cells to the extracellular matrix so as to cause a relaxation of the cells. If this Group is elected, a further restriction is required as detailed below.

Page 3

- Group III. Claim 12, drawn to a method for manipulating the intrinsic strain of cells, comprising treating the cells with compounds that affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is hyaluronic acid which reduces extracellular matrix modeling.
- Group IV. Claims 13 and 14, drawn to a method for manipulating the intrinsic strain of cells, comprising treating the cells with compounds that affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is a cytokine which adjusts the intrinsic strain of cells by

Application/Control Number: 10/570,125

Art Unit: 1635

modulating gene expression. If this Group is elected, a further restriction is required as detailed below.

Page 4

Group V. Claim 15, drawn to a method for manipulating the intrinsic strain of cells, comprising treating the cells with compounds that affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is a compound that interferes with actin polymerization to decrease the modulus of the cells and thus decrease its intrinsic strain. If this Group is elected, a further restriction is required as detailed below.

Group VI. Claim 16, drawn to a method for manipulating the intrinsic strain of cells, comprising treating the cells with compounds that affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is nocodazole which disrupts the microtubular network and thus increases cell modulus.

Group VII. Claims 17 and 18, drawn to a method for manipulating the intrinsic strain of cells, comprising treating the cells with compounds that

affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is an interfering RNA compound to cytoskeletal genes that regulate the intrinsic strain setpoint of the cells.

Claims 1-7 links inventions of Groups I-VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-7. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application does not comply with the requirements of unity of invention (Rules 13.1, 13.2, and 13.3) for the following reasons:

The inventions listed as Groups I-VII do not relate to a single general inventive

concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or

corresponding special technical feature for the following reasons:

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT

Page 6

Administrative Instructions, the special technical feature as defined by PCT Rule 13.2

shall be considered to be met when all the alternatives of a Markush-group are of

similar nature. For chemical alternatives, compounds that affect the intrinsic strain

setpoint of the cells in order to modulate extracellular matrix synthesis, secretion,

stiffness, organization and/or remodeling, or attachment of the cells to the matrix via

integrins or other like cell-matrix attachments, the Markush group shall be regarded as

being of similar nature when:

(A) all alternatives have a common property or activity and

(B)(1) a common structure is present, i.e., a significant structure is shared by all

of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all

alternatives belong to an art-recognized class of compounds in the art to which the

invention pertains.

The claimed methods of using compounds that affect the intrinsic strain setpoint

of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness,

organization and/or remodeling, or attachment of the cells to the matrix via integrins or

other like cell-matrix attachments listed in Groups I-VII do not meet the criteria of (B)(1),

where a common structure is present, i.e., a significant structure is shared by all of the

alternatives. The special technical feature of methods of using said compound listed in

Groups I-VII do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the claimed methods of using compounds that affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments listed in Groups I-VII is lacking and each special technical feature compound listed in each Group is considered to constitute a special technical feature.

Page 7

Thus, in summary, each of Groups I-VII is directed to different special technical features, namely distinct and independent methods of using compounds that affect the intrinsic strain setpoint of the cells, and thus supports this lack of unity.

If Group I is elected, claim 9 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Hamish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3

USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Page 8

Claim 9 specifically claims a method for manipulating the intrinsic strain of cells, comprising treating the cells with compounds that affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is a mediator which causes release of cell attachment points of the cells from its extracellular matrix, and wherein the mediator is a binding site peptide such as collagen, fibronectin or a laminin-binding site peptide such as decorin, biglycan, fibromodulin, and lumican. Although the mediators are all binding site peptides, the instant binding site peptides are considered to be unrelated, since each binding site peptide used in the methods as claimed is structurally and functionally independent and distinct for the following reasons: each binding peptide is a unique and different protein. As such the Markush/genus of binding site peptides used in the method claims of claim 9 is not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the binding site peptides claimed in the method of claim 9 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed binding site peptides. In view of the foregoing, one (1) binding site peptide is considered to be a reasonable number for examination. Accordingly, if Applicants elect Group I, Applicants

are required to elect one binding site peptide from claim 9. That is, Applicants are required to elect either collagen, fibronectin, decorin, biglycan, fibromodulin, or lumican. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally different binding site peptides.

If Group II is elected, claim 11 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 11 specifically claims a method for manipulating the intrinsic strain of cells, comprising treating the cells with compounds that affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness,

organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is a ligand that modulates attachment and tensional structuring of the cells to the extracellular matrix so as to cause a relaxation of the cells, and wherein the ligand is selected from the group consisting of adenosine triphosphate. adenosine diphosphate. adenosine monophosphate, uridine triphosphate, uridine diphosphate, uridine monophosphate and uridine triphosphate. Although the ligands are all nucleotide phosphates, the instant nucleotide phosphates are considered to be unrelated, since each nucleotide phosphate used in the methods as claimed is structurally and functionally independent and distinct for the following reasons: each nucleotide phosphate has a unique and different chemical structure. As such the Markush/genus of nucleotide phosphates used in the method claims of claim 11 is not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the nucleotide phosphates claimed in the method of claim 11 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed nucleotide phosphates. In view of the foregoing, one (1) nucleotide phosphate is considered to be a reasonable number for examination. Accordingly, if Applicants elect Group II, Applicants are required to elect one nucleotide phosphate from claim 11. That is, Applicants are required to elect either adenosine triphosphate, adenosine diphosphate, adenosine monophosphate, uridine triphosphate, uridine diphosphate, or uridine monophosphate and uridine triphosphate. Note that this is not a species election but a restriction of

distinct and independent inventions: unique and chemically different nucleotide phosphates.

If Group IV is elected, claim 14 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 14 specifically claims a method for manipulating the intrinsic strain of cells, comprising treating the cells with compounds that affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is a cytokine which adjusts

the intrinsic strain of cells by modulating gene expression, and wherein the cytokine is selected from the group consisting of interleukin-1 beta and tumor necrosis factor-alpha. Although the cytokines all adjust the intrinsic strain of cells by modulating gene expression, the instant cytokines are considered to be unrelated, since each cytokine used in the methods as claimed is structurally and functionally independent and distinct for the following reasons: each cytokine is known in the art to possess a unique and different nucleotide sequence. As such the Markush/genus of cytokines that modulate gene expression used in the method claims of claim 14 is not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the cytokines claimed in the method of claim 14 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed cytokines. In view of the foregoing, one (1) cytokine that modulates gene expression is considered to be a reasonable number for examination. Accordingly, if Applicants elect Group IV, Applicants are required to elect one cytokine from claim 14. That is, Applicants are required to elect either interleukin-1 beta or tumor necrosis factor-alpha. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally different cytokines.

If Group V is elected, claim 15 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be

made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Hamish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 15 specifically claims a method for manipulating the intrinsic strain of cells, comprising treating the cells with compounds that affect the intrinsic strain setpoint of the cells in order to modulate extracellular matrix synthesis, secretion, stiffness, organization and/or remodeling, or attachment of the cells to the matrix via integrins or other like cell-matrix attachments, wherein the compound is a compound that interferes with actin polymerization to decrease the modulus of the cells and thus decrease its intrinsic strain, and wherein the compound is selected from the group consisting of cytochalasin D, cytochalasin B, and colchicines. Although the compounds all interfere with actin polymerization to decrease the modulus of the cells and thus decrease its intrinsic strain, the instant compounds are considered to be unrelated, since each compound used in the methods as claimed is structurally and functionally independent

Application/Control Number: 10/570,125 Page 14

Art Unit: 1635

and distinct for the following reasons: each compound is known in the art to possess a unique and different chemical structure. As such the Markush/genus of compounds that interfere with actin polymerization to decrease the modulus of the cells and thus decrease its intrinsic strain used in the method claims of claim 15 is not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the compounds claimed in the method of claim 15 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed compounds. In view of the foregoing, one (1) compound that interferes with actin polymerization to decrease the modulus of the cells and thus decrease its intrinsic strain is considered to be a reasonable number for examination. Accordingly, if Applicants elect Group V, Applicants are required to elect one compound from claim 15. That is, Applicants are required to elect either cytochalasin D, cytochalasin B, or colchicines. Note that this is not a species election but a restriction of distinct and independent inventions: unique and chemically different compounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above <u>and</u> there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

Application/Control Number: 10/570,125

Art Unit: 1635

(b) the inventions require a different field of search (for example searching electronic resources, or employing different search queries);

Page 15

- (c) the prior art applicable to one invention would not likely be applicable to another invention;
- (c) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

Application/Control Number: 10/570,125 Page 17

Art Unit: 1635

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

September 17, 2008 /Terra Cotta Gibbs/

Application Number

| Application/Control No. | Applicant(s)/Patent under Reexamination |  |
|-------------------------|---|--|
| 10/570,125              | BANES ET AL.                            |  |
| Examiner                | Art Unit                                |  |
| TERRA C. GIBBS          | 1635                                    |  |